Louisiana Medicaid
Idiopathic Pulmonary Fibrosis

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for idiopathic pulmonary fibrosis agents.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Nintedanib (Ofev®)

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has **ONE** of the following diagnoses:
    - idiopathic pulmonary fibrosis (IPF); **OR**
    - chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype; **OR**
    - systemic sclerosis-associated interstitial lung disease (SSc-ILD); **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The recipient is established on the medication with positive clinical outcomes; **AND**
- Nintedanib (Ofev®) is prescribed by, or the request states that this medication is being prescribed in consultation with, a pulmonologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Pirfenidone (Esbriet®)

Approval Criteria

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of idiopathic pulmonary fibrosis (IPF); **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The recipient is established on the medication with positive clinical outcomes; **AND**
- Pirfenidone (Esbriet®) is prescribed by, or the request states that this medication is being prescribed in consultation with, a pulmonologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 3 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

References

Esbriet (pirfenidone) [package insert]. San Francisco, CA: Genentech, Inc. a trademark of Roche; July 2019. https://www.gene.com/download/pdf/esbriet_prescribing.pdf

Ofev (nintedanib) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; October 2020. https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Ofev/ofev.pdf

Revision / Date	Implementation Date
Policy created	July 2020
Combined Esbriet® and Ofev® clinical criteria, formatting changes and updated references / November 2020	January 2021
Formatting changes / September 2021	January 2022